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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/580,476	05/26/2000	Edwin G. Westaway	37264.6.0	8898

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EXAMINER

GUZO, DAVID

ART UNIT PAPER NUMBER

1636

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/580,476

Applicant(s)

WESTAWAY ET AL.

Examiner

David Guzo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-5, 7-9, 15-21, 24, 25, 33-36 and 49-65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-5, 7-9, 15-21, 24, 25, 33-36 and 49-65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 September 2003 and 09 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Detailed Action

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-5, 7-9, 15-21, 24-25, 33-36 and 49-65 are rejected under 35

U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7, 21, 35, 36, 55, 56 and 65 (and dependent claims) are vague in that applicants recite a vector which "...is adapted to receive..." or "...is adapted to include..." a nucleotide sequence. It is unclear what adaptations or changes are necessary for the vector to receive (or include) the nucleotide sequences, i.e. does the vector need to be altered in some undisclosed fashion(s) to allow for the inclusion of the nucleotide sequence(s)?

Claims 15 and 51 are vague in the recitation of the phrase "vector RNA with precise 3' terminus possessing high replication efficiency." It is unclear what "precise 3' terminus" is referred to in the claim. It is unclear what the relationship is between the "precise 3' terminus" and the "high replication efficiency" of the vector. Also, the phrase "possessing high replication efficiency" appears disconnected from the rest of the claim, it should be connected with use of the word "and" placed between "terminus" and "possessing".

Claims 21 and 65 are vague in the recitation of the phrase "part or all of a structural protein(s) region". It is the "region" of the structural protein which can be

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single or plural here. Redrafting the claim to recite “part or all of one or more structural proteins” would be remedial.

Claim 25 is vague in the recitation of the word “alphaviru l”.

Claim 35 is vague in the recitation of the phrase “...substantially all of the nonstructural region...” because the word “substantially” is a subjective term with no standard for comparison, i.e. substantially compared to what standard. The metes and bounds of the claimed invention are therefore unclear.

Claim 50 is vague in the recitation of the phrase “comprising a eucaryotic expression promoter is a cytomegalovirus early enhancer promoter region” as this makes no sense.

Claim 55 is vague in the recitation of a replicon vector “...adapted to receive at least a nucleotide sequence...”. The metes and bounds of the claimed subject matter are unclear because the “at least” language leaves the claim open to inclusion of undisclosed non-nucleotide molecules into the vector. Possibly, applicants mean to recite “at least one nucleotide sequence”. Claim 55 is also vague in the recitation of the phrase “...nucleotide sequence **does not encode for** (emphasis added) the structural protein sequence...” because the language used is cumbersome and confusing. Redrafting the claim to recite “nucleotide sequence does not encode the structural protein sequence...” would be remedial.

Claim 58 is vague in that there is no antecedent basis for the phrase “nucleotide sequence that is inserted into the 3’ UTR of the replicon” in claim 65. The claim should be dependent on claim 57.

Claim 60 is vague in the recitation of the phrase "is inserted in place of at least a deleted structural gene", it is unclear if the "at least" language used means that the nucleotide sequence is to be inserted into at least one or more deleted structural genes or is to be inserted into a deletion of any region of the genome wherein said deletion encompasses a structural gene.

Claim 61 is vague in that there is no antecedent basis for the term "the nucleotide sequence that is inserted in place of deleted structural proteins of the replicon" in claim 65. Claim 61 should be dependent on claim 60.

The substitute drawings filed 9/17/03 are approved.

The substitute Figure 2 filed 2/9/04 is approved by the examiner.

The Sequence Listing filed 2/9/04 has been entered.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (571) 272-0781. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo
April 21, 2004


DAVID GUZO
PRIMARY EXAMINER